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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/718,112	11/20/2003	Johannes Bartholomaus	107101-10	8885

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EXAMINER	
PERREIRA, MELISSA JEAN	

ART UNIT	PAPER NUMBER
1618	

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Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/718,112	BARTHOLOMAUS ET AL.	
	Examiner	Art Unit	
	MELISSA PERREIRA	1618	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE *3* MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *17 February 2009*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1,2,4,7,8,27-29,31,41 and 42* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1,2,4,7,8,27-29,31,41 and 42* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

Continued Examination Under 37 CFR 1.114

1. A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on 2/17/09 has been entered.

Claims and Previous Rejections Status

2. Claims 1,2,4,7,8,27-29,31,41 and 42 are pending in the application. Claims 41 and 42 were newly added in the amendment filed 2/17/09.

3. The rejection of claims 1,2,4,7,8,27-29 and 31 under 35 U.S.C. 112, second paragraph is withdrawn in view of the declaration of Dr. Johannes Bartholomaus.

4. The rejection of claims 1,2,4,7,8,27-29 and 31 under 35 U.S.C. 103(a) as being unpatentable over Oshlack et al. (US 2003/0064099A1) in view of Zhang et al. (*Pharm. Dev. Tech.* **1999**, *4*, 241-250) and Maggi et al. (Biomaterials **2002**, *23*, 1113-1119) is withdrawn.

5. The rejection of claims 1,2,4,7,8,27-29 and 31 under 35 U.S.C. 103(a) as being unpatentable over Oshlack et al. (US 6,733,783B2) in view of Zhang et al. (*Pharm. Dev. Tech.* **1999**, *4*, 241-250) and Maggi et al. (Biomaterials **2002**, *23*, 1113-1119) is withdrawn.

6. The rejections of claims 1,2,4,6-8,29 and 31 on the ground of nonstatutory obviousness-type double patenting as being unpatentable over applications 11/349,537; 11/462,216; 10/890,763 are withdrawn.

7. The rejection of claims 1,2,4,6-8,29 and 31 on the ground of nonstatutory obviousness-type double patenting as being unpatentable over application 10/567,594 is maintained.

Declaration/Affidavit

8. The declaration under 37 CFR 1.132 filed 2/17/09 is insufficient to overcome the rejection of claims 1,2,4,7,8,27-29 and 31 based upon the reference of Oshlack et al. (US 2003/0064099A1) as set forth in the last Office action because: The reference and examples used to provide the formulations of the comparison tablets (A-2, B-2 and C-2) are not provided/clarified in the declaration of Heinrich Kugelmann, thus it is unclear as to where the applicant obtained the formulation data for tablets A-2, B-2 and C-2. Although, the remarks filed 2/17/09 states that examples 1 and 2 of Oshlack et al. were used for the formulation of the comparison tablets (A-2, B-2 and C-2), the declaration provides no information as to where the formulations were obtained. Also, the example 1 of Oshlack et al. (US 2003/0064099A1) provides 20 mg of oxycodone whereas the formulations A-2, B-2 and C-2 stated in the declaration recites 130 mg of oxycodone, thus it is unclear as to where the applicant obtained the formulation data. Therefore the data provided in the declaration is insufficient to overcome the reference of Oshlack et al. (US 2003/0064099A1)

9. The declaration under 37 CFR 1.132 filed 2/17/09 is insufficient to overcome the rejection of claims 1,2,4,7,8,27-29 and 31 based upon the reference of Oshlack et al. (US 2003/0064099A1) as set forth in the last Office action because: The declaration of Dr. Johannes Bartholomaus states (p5, (b) and p6) that the tablet preparation requires specific preparation temperature and that each PEO polymer of varying molecular weight is required in specific amounts to provide for a breaking strength of 500N and is not commensurate in scope with the instant claims. The instant claims do not provide these necessary limitations (i.e. the specific amounts of each PEO of molecular weight 1-15 million) to distinguish the abuse proof dosage form over the prior art and thus the declaration is insufficient to overcome the rejection of Oshlack et al. (US 2003/0064099A1). Oshlack et al. teaches of the use of PEO polymer in the tablets in a ratio to the opioid agonist of from about 1:15 to about 15:1 weight (p4, [0050]) which encompasses the limitation of component (C) being present in an amount of at least 73 wt.-%. The preparation of the tablets of Oshlack et al. involves a melt-extruded matrix via blending the opioid with PEO, heating to a temperature sufficient to soften the mixture, extruding through a twin-screw extruder and optionally compressing (p9, [0109] and [0111]; p10, [0113] and [0120]) which encompasses the sintering preparation process of the instant claims. Also, the declaration of Dr. Johannes Bartholomaus does not provide for a comparison of the tablets of the instant claims with that of Oshlack et al. containing PEO polymer but only provides for a comparison of the tablets of Oshlack et al. containing Eugragit ® with those of the disclosure.

Terminal Disclaimer

10. The terminal disclaimers filed on 2/17/09 disclaiming the terminal portion of any patent granted on these applications (11/349,537; 11/462,216; 10/890,763) have been reviewed and are accepted. The terminal disclaimers have been recorded.

11. The application/patent being disclaimed has been improperly identified since the number used to identify the application being disclaimed is incorrect. The correct number is 10/567,594.

Double Patenting

12. The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. A nonstatutory obviousness-type double patenting rejection is appropriate where the conflicting claims are not identical, but at least one examined application claim is not patentably distinct from the reference claim(s) because the examined application claim is either anticipated by, or would have been obvious over, the reference claim(s). See, e.g., *In re Berg*, 140 F.3d 1428, 46 USPQ2d 1226 (Fed. Cir. 1998); *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) or 1.321(d) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent either is shown to be commonly owned with this application, or claims an invention made as a result of activities undertaken within the scope of a joint research agreement.

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

13. Claims 1,2,4,6-8,29,31,41 and 42 are provisionally rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 1-

11,25-27 and 36 of copending Application No. 10/567,594. Although the conflicting claims are not identical, they are not patentably distinct from each other because the ingredients, excipients, etc. of the abuse-proofed dosage form, such as opioid drug, polymer and wax of the copending application 10/567,594 encompass those of the instant claims. The tablets of the instant claims and copending application 10/567,594 are in the form of controlled release tablet which are prepared in the same manner (i.e. melt). The polymer characteristics of both tablet formulations, such as molecular weight are identical, therefore allowing for the same breaking strength.

14. This is a provisional obviousness-type double patenting rejection because the conflicting claims have not in fact been patented.

New Grounds of Rejection

Claim Objections

15. Claim 1 is objected to because of the following informalities: The instant claim ends in two periods. Appropriate correction is required.

Response to Arguments

16. Applicant's arguments with respect to claims 1,2,4,7,8,27-29,31,41 and 42 have been considered but are moot in view of the new ground(s) of rejection.

Claim Rejections - 35 USC § 103

17. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

18. Claims 1,2,4,7,8,27-29,31,41 and 42 are rejected under 35 U.S.C. 103(a) as being unpatentable over Oshlack et al. (US 2003/0064099A1).

19. Oshlack et al. (US 2003/0064099A1) discloses a sustained release dosage form which comprises a.) oxycodone, b.) an aversive agent/gelling agent, such as polyethylene oxide, c.) waxes, etc. (p2, [0026]; p8, [0097]; p9, [0106-0111]; p4-5 [0049] and [0056]). The PEO polymer may be present in the tablets in a ratio to the opioid agonist of from about 1:15 to about 15:1 by weight (p4, [0050]) which encompasses the limitation of component (C) being present in an amount sufficient to result in a breaking strength of at least 500N, such as of at least 73 wt.-% of the instant claims. The dosage form may be prepared via melt-extrusion techniques which involves blending the opioid with PEO to form a matrix, heating the matrix to a temperature sufficient to soften the mixture, extruding through a twin-screw extruder and optionally compressing (p8, [0096]; p9, [0109] and [0111]; p10, [0113] and [0120]). The melt-extrusion technique of Oshlack et al. encompasses the sintering technique of the instant claims where the dosage form components are mixed and the resultant mixture is press-formed with preceding exposure to heat. Suitable controlled release tablets may be formulated from multiparticulate formulations, wet granulation that is compressed into a tablet or melt and may contain hydrophobic binders, such as carnauba wax (p8, [0099]; p9, [0110-0111]; p10, [0120]). Oshlack et al. does not explicitly disclose the dosage form having a breaking strength of at least 500N.

20. At the time of the invention it would have been obvious to one skilled in the art that the opioid and PEO polymer dosage form of Oshlack et al. prepared via a melt-extrusion technique, which encompasses the sintering preparation process of the instant claims, contains the PEO polymer in an amount sufficient to result in a breaking strength of at least 500N as the PEO polymer may be present in the tablets in a ratio to the opioid agonist of from about 1:15 to about 15:1.

21. Therefore, if the prior art teaches the composition, then the properties are also taught by the prior art. In re Spada, 911 F.2d 705, 709, 15 USPQ 1655, 1658 (Fed. Cir. 1990.) See MPEP 2112.01. The burden is shifted to Applicant to show that the prior art product does not possess or render obvious the same properties as the instantly claimed product as the instant claims do not provide the necessary limitations to distinguish the abuse proof dosage form over the prior art.

22. It is respectfully pointed out that instant claim 29 is a product-by-process limitations. Even though product-by-process claims are limited by and defined by the process, determination of patentability is based on the product itself. The patentability of a product does not depend on its method of production. If the product in the product-by-process claim is the same as or obvious from a product of the prior art, the claim is unpatentable even though the prior product was made by a different process. In re Thorpe, 777 F.2d 695, 698, 227 USPQ 964, 966 (Fed Cir. 1985). See MPEP 2113.

Conclusion

No claims are allowed at this time.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to MELISSA PERREIRA whose telephone number is (571)272-1354. The examiner can normally be reached on 9am-5pm M-F.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Mike Hartley can be reached on 571-272-0616. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Michael G. Hartley/
Supervisory Patent Examiner, Art Unit 1618

/Melissa Perreira/
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